REMARKS

Reconsideration of this application is requested. Claims 113-133 are active in this application subsequent to entry of this amendment.

Elected Subject Matter -1, 2

In the Official Action a number of claims have been withdrawn from further consideration as being directed to non-elected subject matter. While these claims remain in the case those claims directed to elected subject matter have been replaced with a new set of claims.

The basis for the new claims is as follows:

New claims	Support
113	Old claims 1, 4, 5, and page 2, line 12
114	Old claim 3
115	Old claim 2
116	Old claims 6 and 72
117	page 7, (lines 20 to 23), page 25, (lines 13 to 16), and page 26, (lines 23 to 27)
118	page 5(line 18)
119	Old claims 42, 4, 5 and page 12 line 12
120	Old claim 51
121	Old claim 53
122	Old claims 77 and 81
123-127	Old claims 78 to 80
128-133	Page 26, lines 19 to 28

35 USC 112, first paragraph - 3-11[1]

The examiner questions an erodable silicon implant as claimed and suggests that old claim 1 contains subject matter that is not described in the specification in such a manner as to convey that the inventor had possession of the claimed invention. The examiner requests clarification. Old claim 1 is directed to a silicon implant that is eroded when implanted in a mammalian body. The examiner's objection to old claim 1, under this heading, is based on the fact that certain forms of silicon are not erodable when implanted.

The examiner believes that the wording of old claim 1 is contradictory. The fact that the old claim 1 implant is erodable, according to the examiner, contradicts the fact that certain forms of silicon are not erodable.

The new wording of new claim 113 is directed to an implant comprising resorbable silicon. The property of erosion in a mammalian body is associated, in the new claim 113 wording, only with those forms of silicon that are erodable.

35 USC 112, second paragraph and USC 101 - 12

In response to the examiner's comments at paragraphs 6 to 11 of the letter, counsel has withdrawn the claims which were the subject of objections contained in these paragraphs.

35 USC 102 - 13-14

The examiner believes that WO 97/06101 (WO'101) and US 5,797,898 (US'898) deprive old claim 1 of novelty. Old claim 1 has been amended, and applicants submit new claim 113 is novel over these two items for the reasons given below.

WO'101

WO'101 describes *in vitro* experiments in which porous silicon is found to be resorbable (paragraph spanning pages 12 and 13). WO'101 does not disclose an implant comprising resorbable silicon that has been associated with a beneficial substance. Further, WO'101 also does not disclose tissue compatibility, since the structure of the

[1] identifies the numbered items in the Action

resorbable silicon found to be tissue compatible (in the present application) differs from that disclosed in WO'101 (page 14, lines 17 to 19 of the present application, and page 12, lines 31 to 33 of WO'101). Therefore WO'101 does not deprive new claim 113 of novelty.

US'898

This citation discloses microchip devices having at least two reservoirs that are formed in a substrate, each reservoir having a reservoir cap (claim 1). The devices may be used as drug delivery devices, and the reservoir caps may degrade over time. The cap material is preferably polymeric (column 5, lines 30 to 34). Alternatively the cap may be formed from a conductive material such as a metal or certain forms of polymer (column 8, last three lines). The substrate may be biocompatible, but biocompatibility is not required (column 3, lines 55 to 56). The substrate material used in the specific embodiment is a silicon wafer (column 7, line 8). The unit is encapsulated in a biocompatible coating such as poly(ethyleneglycol) (column 10, lines 25 to 26). US'898 does not disclose the use of resorbable silicon. US'898 does not disclose the use of tissue compatible resorbable silicon. Therefore US'898 does not deprive new claim 113 of novelty.

35 USC 103 - 15-21

WO'101

Paragraph 19 of the Office Action is a duplicate of paragraph 14, already addressed above. The examiner cites WO'101 under USC 102(b). Presumably the examiner intended to cite WO'101 in relation to USC 103. The following is therefore an explanation of why new claim 113 is inventive over the WO'101 disclosure.

There is nothing in WO'101 to suggest that certain forms of resorbable silicon are tissue compatible. There is nothing in WO'101 to suggest the combination of tissue compatible resorbable silicon with a beneficial substance.

The last sentence of the paragraph spanning pages 16 and 17 of WO'101 states that tissue compatibility is associated with the deposition of apatite, and that this may act

as a protective barrier. This sentence from WO'101 would discourage the skilled person from performing experiments to investigate tissue compatibility in connection with resorbable silicon for drug delivery. This is because tissue compatibility is associated with the formation of a protective barrier that could inhibit the delivery of the drug.

Even in the event that a tissue compatibility experiment were performed, it would still not be obvious that resorbable silicon would be tissue compatible. This is because it is not possible to predict the response of a mammalian body to resorbable silicon. The impossibility of predicting such a response is discussed in WO'101 at page 17, lines 16 to 24:

> "...the behavior of a porous silicon region in a living body may be affected by factors which are not reproducible in the SBF solution. If living cells grow on the surface of the porous silicon, these cells may interact with the porous silicon. Thus experiments carried out in the SBF solution do not provide a clear indication of the suitability of a particular form of porous silicon for resorbable material applications."

It follows that claim 113 is inventive over the disclosure of WO'101.

US'898

The examiner believes that old claim 1 is obvious from the US'898 disclosure. Claim 1 has been amended and new claim 113 is not obvious in relation to the US'898 disclosure for the reasons given below.

US'898 discloses the use of bulk crystalline silicon in the form of a silicon wafer (column 7, line 8). The silicon substrate has to be encapsulated with a biocompatible material (column 10, line 25 to 26). In other words, the silicon wafer by itself is not biocompatible (see column 3, lines 56 to 59).

The preferred resorbable materials described in connection with the US'898 implants are selected from the following: biodegradable polymers, bioerodable hydrogels, proteins (column 4, lines 44 to 46), and metals (column 8, line 3). The reservoir cap may be formed from a polymer (column 3, lines 33 to 34) such as a UV polymerizable polymer (column 8, line 37).

The fact that US'898 silicon implant has to be encapsulated to confer biocompatibility, and the fact that US'898 expresses a preference for metallic, polymeric, or protein resorbable materials, would lead the skilled person away from the claimed invention. In other words, the US'898 disclosure would lead the skilled person away from using silicon as a resorbable material, and would lead the skilled person away from investigating the biocompatibility of silicon. Therefore new claim 113 is inventive over US'898.

US'898 and US'060

The examiner cites, at paragraph 21, US 3,919,060 (US'060). This document is cited because it describes the anodization of silicon in aqueous HF solutions to yield porous silicon (paragraph spanning columns 3 and 4 of US'060). For the purposes of the US'060 invention the porosity should be greater than 40 % and most preferably of the order of 56 %. US'060 does not provide any information as to the pore size. In other words US'060, does not provide information about whether the porous silicon is microporous, mesoporous, or macroporous.

The examiner combines US'898 with US'060, presumably because US'898 does not disclose porous silicon. However, neither of US'060 and US'898 disclose resorbable porous silicon, let alone tissue compatible resorbable silicon. The combination of references fails as the result does not satisfy the features claimed. Therefore new claim 113 is patentable over US'898 in view of US'060.

Background discussion relating to the biological properties of silicon

WO'101 describes the properties and uses of a number of forms of silicon. Experience has shown that it is sometimes possible to confuse these different types of material. To clarify the discussions, applicants wish to draw the examiner's attention to the definitions and discussion provided in this item of prior art.

Bioactive silicon

Bioactive silicon is silicon that, *in vivo*, elicits the formation of a bond between living tissue and the material (page 1, lines 10 to 12 of WO'101).

Resorbable silicon

Bioactive silicon should not be confused with resorbable silicon, which is silicon that is designed to gradually degrade over time, when placed in host tissue (page 17, lines 6 to 7 of WO'101).

Porous silicon

Porous silicon may be subdivided according to the nature of the porosity. Microporous silicon contains pores having a diameter less than 20 A; mesoporous silicon contains pores having a diameter in the range 20 A to 500 A; and macroporous silicon contains pores having a diameter greater than 500 A (page 3, lines 23 to 28 of WO'101).

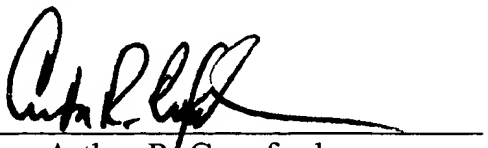
The effect of porosity of biological properties

Bulk and purely macroporous silicon are relatively bioinert; high porosity mesoporous silicon is resorbable and micrporous silicon of moderate porosity is bioactive (WO'101, page 13, lines 26 to 28).

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

Arthur R. Crawford
Reg. No. 25,327

ARC:pfc
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100